

REMARKS

This is in response to the Office Action mailed on April 3, 2009, in which claims 1-5 and 8-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent App. Pub. No. 2003/0153819 (*Iliff*), in view of U.S. Patent No. 5,941,829 (*Saltzstein*), in view of U.S. Patent App. Pub. No. 2002/0026103 (*Norris*), and further in view of U.S. Patent No. 5,857,194 (*Kelliher*); claims 6 and 7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iliff*, in view of *Saltzstein*, in view of *Norris*, in view of *Kelliher*, and further in view of U.S. Patent No. 6,250,309 (*Krichen*); claims 18, 19, 21-24, 28, 29 and 31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iliff*, in view of *Norris*, and further in view of *Kelliher*; claims 20 and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iliff*, in view of *Norris*, in view of *Kelliher*, and further in view of *Saltzstein*; and claim 25 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iliff*, in view of *Norris*, in view of *Kelliher*, and further in view of *Krichen*. Claims 1-13, 18-25, and 28-31 are pending in the present application.

Claim Rejections – 35 U.S.C. § 103

Claims 1-5 and 8-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iliff*, in view of *Saltzstein*, in view of *Norris*, and further in view of *Kelliher*. Claim 1 is directed to a system for automatically populating medical device data into one or more databases. The system includes a system controller including a processor and a computer readable medium, the latter of which includes instructions executable by the processor to, in part, receive data sets comprising objective and subjective data about a first patient collected by a physician. Claim 9 is directed to a medical device information system including, in part, means for receiving objective data and subjective data collected by a physician about a first patient.

Iliff discloses a system and method for performing a computerized medical correlation assessment involving an automated process for managing a specified health problem. The system performs disease management in a fully automated manner, using periodic interactive dialogs with the patient to obtain health state measurements from the patient, to evaluate and

assess the progress of the patient's disease, to review and adjust therapy to optimal levels, and to give the patient medical advice for administering treatment and handling symptom flare-ups and acute episodes of the disease. Subjective and objective health measurements are used to determine a metric, which can be used to adjust patient therapy.

As acknowledged on page 3 of the Office Action, *Iliff* does not teach or suggest, among other elements, that subjective and objective data sets are collected by a physician. To supply the deficiencies of *Iliff*, the Office Action turns to the teachings of *Saltzstein*, *Norris*, and *Kelliher*. Particularly, the Office Action cites the disclosure at col. 5, lines 47-53 of *Saltzstein*, which discusses transmitting data and voice communications relating to treatment of a patient in real time to a physician to account and correct for the patient's current physical and emotional state. However, this combination is not proper.

In providing the background for his invention, *Iliff* discuss that "[a]lmost all 'knowledge based' clinical reasoning could be performed better and more reliably by computers." *Iliff*, para. 0012. According to *Iliff*, "[a] system that can automate the practice of medicine, especially in disease management, and which encourages and trains patients to play a major beneficial role in their medical health care is highly desired." *Id.* Disease management, *Iliff* notes, "attempts to take the practice of medicine out of the hands of physicians and puts it into the hands of patients." *Iliff*, para. 0011. Thus, *Iliff* teaches away from the proposed combination with *Saltzstein*. In particular, modifying *Iliff*'s system to involve a physician in the collection of subjective and objective data from a patient, as suggested by the Office Action, would completely change the principle of operation of *Iliff*'s system, since physician involvement is precisely what *Iliff*'s system is trying to avoid. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teaching of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.01(VI), citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Therefore, because the proposed modification of *Iliff* is not proper, it is respectfully submitted that the rejection of claims 1 and 9 under 35 U.S.C. § 103(a) should be withdrawn.

In addition, it is respectfully submitted that the combinations of features recited in claims 2-5, 8, and 10-13, which are allowable with their respective independent base claims, are patentable on their own merits. However, this does not need to be specifically addressed herein since any claim depending from a patentable independent claim is also patentable.

Claims 18, 19, 21-24, 28, 29 and 31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iliff*, in view of *Norris*, and further in view of *Kelliher*. Claims 18 and 28 relate to a system and method, respectively, for automatically populating medical data into a database. First and second data sets are received from an implantable medical device and have first and second data and time stamps, respectively, associated with them. The first and second data sets are automatically populated into a database having one more database records associated with the patient, and the first and second date and time stamps are configured to act as record locators associated with the patient.

As noted by the Office Action on page 8, *Iliff* does not teach or suggest, among other elements, that first and second data sets are received from an implantable medical device. To supply the deficiencies of *Iliff*, the Office Action turns to the teachings of *Norris* and *Kelliher*. Particularly, the Office Action cites the disclosure of *Norris* at paragraph 0079, which discusses the uploading of data from an IMD for analysis. However, a person of ordinary skill in the art would not make this combination.

Iliff is directed to an interactive disease management system that allows a user to communicate with the system by telephone or over a computer. The system asks a series of questions to provide continuing medical care to the user, who has previously been diagnosed with a disease. The system builds a profile for the user in the form of the frequency and reasons for contacts with the system, the user's subjective understanding of the disease, the patient's objective response to various medical treatments, and the patient's preferences in treatment. *Iliff*, paragraph 0125. All subjective data is provided by the patient by answering questions, and all objective data is provided by the patient based on measurements performed by the patient. *Iliff*, paragraph 0158. This is pursuant to the goal of *Iliff*'s system, which is to "take the practice of medicine out of the hands of physicians and puts it into the hands of patients." *Iliff*, para. 0011-0012 Modifying *Iliff*'s system as proposed to include an IMD and

to obtain information from the IMD would take a substantial portion of the disease management out of the hands of the patient, which teaches away from the stated goal of *Iliff*'s system discussed above. In addition, even if an IMD with data transfer capabilities were incorporated into *Iliff*'s system, it is unclear how data transferred from the IMD would be used in *Iliff*'s system, since *Iliff* does not teach or suggest that the described disease management system has the capability to process or analyze IMD data. Therefore, because a person of ordinary skill in the art would not combine *Iliff*, *Norris*, and *Kelliher* to arrive at the claimed invention, it is respectfully submitted that the rejection of claims 18 and 28 under 35 U.S.C. § 103(a) should be withdrawn.

In addition, it is respectfully submitted that the combinations of features recited in claims 19, 21-24, 29 and 31 are patentable on their own merits, although this does not need to be specifically addressed herein since any claim depending from a patentable independent claim is also patentable. For example, the proposed modification of *Iliff* with the teachings of *Norris* and *Kelliher* with regard to claims 19 and 29 is improper for reasons similar those discussed above with regard to the claims 1 and 9, and the combination of *Iliff*, *Saltzstein*, *Norris*, and *Kelliher*.

Claims 6 and 7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iliff*, in view of *Saltzstein*, in view of *Norris*, in view of *Kelliher*, and further in view of *Krichen*; claims 20 and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iliff*, in view of *Norris*, in view of *Kelliher*, and further in view of *Saltzstein*; claim 25 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iliff*, in view of *Norris*, in view of *Kelliher*, and further in view of *Krichen*. None of the cited references cure the deficiencies discussed above with respect to claims 1, 18, and 28. In addition, claims 6 and 7 depend from allowable claim 1, claims 20 and 25 depend from allowable claim 18, and claim 30 depends from allowable claim 28. As such, these claims are allowable with their respective independent base claims. In addition, it is respectfully submitted that the combinations of features recited in claims 6, 7, 20, 25, and 30 are patentable on their own merits, although this does not need to be specifically addressed herein since any claim depending from a patentable independent claim is also patentable.

CONCLUSION

For the reasons explained above, all pending claims are now in condition for allowance. Accordingly, the applicant respectfully requests that the Office issue a Notice of Allowance.

Any amendments to the claims are made to expedite prosecution of this application, without acquiescing to the Office's rejections or characterizations of the claims or references in the Office Action. Even if not expressly discussed above, the applicant respectfully traverses each of the rejections, assertions, and characterizations regarding the disclosure and teachings of the cited references, including the prior art status and the propriety of proposed combinations of cited references.

The Applicant has made a good faith effort to respond to all rejections set forth in the Office Action and to place the pending claims in condition for immediate allowance. If it would be helpful, the Examiner is invited to contact the undersigned at the number listed below to facilitate prosecution of this application.

Respectfully submitted,

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Dated: July 1, 2009

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